OCT 2 5 2001

510(k) Summary of Safety and Effectiveness
ArthroCare Corporation
ArthroCare® Electrosurgery Wands

K012519

General Information

Manufacturer:

ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94085-2936

Establishment Registration Number: 2951580

Contact Person:

Bruce Prothro
Vice President Regulatory Affairs, Quality Assurance, and Clinical Research

Date Prepared: August 3, 2001

Device Description

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Trade Name: ArthroCare® Electrosurgery Wand

Generic/Common Name: Electrosurgical Device and Accessories

Predicate Devices

- ArthroCare Electrosurgery System K001302
- Ethicon PowerStar Bipolar Scissors K981361
- Coherent VersaPulse Select Single Wavelength (Ho:YAG) Dual Wavelength (Ho:YAG/Nd:YAG) Laser System K990947

Intended Use

The Electrosurgery Wands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in open, laparoscopic, and endoscopic general surgery and general gynecology procedures. Representative procedures may include the following:

General Surgery
• cholecystectomy
• lysis of adhesions
• upper GI
• GI (other)
• splenectomy
• thyroidectomy
• herniorrhaphy
• breast biopsy
• bowel resection
• pelvic adhesiolysis
• removal of lesions
• removal of polyps
• tumor biopsy
Gynecological Surgery
• lysis of adhesions
• hysterectomy
• salpingo-oophorectomy
• burch colposuspension
• myomectomy
• endometriosis
• ovariohysterectomy
• removal of tumors

Product Description

The ArthroCare Electrosurgery Wands are single use, disposable bipolar electrosurgical devices designed to be used in conjunction with the ArthroCare Electrosurgery System (System 2000).

Substantial Equivalence

In establishing substantial equivalence to the predicate devices, ArthroCare evaluated the indications for use, materials, technology, product specifications, and energy requirements of those systems. Additionally, performance testing has been completed to demonstrate the safe and effective use of the Electrosurgery Wands in the resection and ablation of soft tissue. The performance testing and device comparison demonstrated that the subject devices are substantially equivalent to the predicate devices, and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2001

Mr. Bruce Prothro
Vice President Regulatory Affairs,
Quality Assurance and Clinical Research
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94085

Re: K012519
Trade/Device Name: ArthroCare® Electrosurgery Wand
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 3, 2001
Received: August 6, 2001

Dear Mr. Prothro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: ArthroCare® Electrosurgery Wands
510(k) Number: K012519

Indications for use:

The ArthroCare Electrosurgery Wands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in open, laparoscopic, and endoscopic general surgery and general gynecology procedures. Representative procedures may include the following:

General Surgery
• cholecystectomy
• lysis of adhesions
• upper GI
• GI (other)
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• thyroidectomy
• herniorrhaphy
• breast biopsy
• bowel resection
• pelvic adhesiolysis
• removal of lesions
• removal of polyps
• tumor biopsy
Gynecological Surgery
• lysis of adhesions
• hysterectomy
• salpingo-oophorectomy
• burch colposuspension
• myomectomy
• endometriosis
• ovariohysterectomy
• removal of tumors

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walke

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use (Per 21 CFR 801.109) X OR Over-the-Counter Use

510(k) Number K012519